

K172096 FraxisAug 9, 2017
29 days to decisionK172096 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k172096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 11, 2017
Decision date	Aug 9, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ilooda Co.,, Ltd.
Location	Gwonseon-Gu, Suwon-Si, KR
Contact	Kathy Maynor
510(k) history	16 submissions · 16 cleared · 2015-2024

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